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## 510 (k) SUMMARY

### I. ADMINISTRATIVE

**Submitter:**

Ferndale Laboratories, Inc.  
780 W. 8 Mile Rd  
Ferndale, Michigan 48220  
(248) 548-0900

JAN 12 2007

**Contact Person:** Richard A. Hamer

**Date of Preparation:** February 3, 2006

### II. DEVICE NAME

**Proprietary Name:** Locobase® Wound and Skin Emulsion

**Common Name:** Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic

**Classification Name:** Dressing, Wound and Burn, Hydrogel w/Drug and/or Biologic

### III. PREDICATE DEVICES

Biafine™ Wound Dressing Emulsion (K964240) Medix Pharmaceuticals America, Inc.  
Sinclair (Atopiclair™) Wound and Skin Emulsion (K024367) Sinclair Pharmaceuticals, Ltd.

MimyX™ Cream (K041342) Stiefel Laboratories, Inc.

### IV. DEVICE DESCRIPTION

Locobase® Wound and Skin Emulsion is a semi-viscous emulsion/cream formulation intended for topical application supplied non-sterile in 30 g and 100g tubes.

### V. INTENDED USE

Under the supervision of a healthcare professional, the product is intended for the management and relief of burning, itching and redness associated with atopic dermatitis. The product, when applied topically to the affected area, forms a protective barrier that helps keep the skin moist, which has a beneficial effect on the healing process.

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## VI. COMPARISON TO PREDICATE DEVICES

Locobase® Wound and Skin Emulsion is similar in composition, function and intended use to other legally marketed hydrogel wound dressing products, such as Biafine™ Wound Dressing Emulsion (K964240) Medix Pharmaceuticals America, Inc., Sinclair (Atopiclair™) Wound and Skin Emulsion (K024367) Sinclair Pharmaceuticals, Ltd., and MimyX™ Cream (K041342) Stiefel Laboratories, Inc. All referenced products are non-sterile viscous emulsions/creams that are applied topically to manage and relieve symptoms of various dermatoses.

## VII. CONCLUSION

Functional and performance testing has been conducted to assess the safety and efficacy of Locobase® Wound and Skin Emulsion.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ferndale Laboratories, Inc.  
Attn: Mr. Richard A. Hamer  
Vice President, Regulatory/Clinical  
Affairs and Quality Assurance  
780 West Eight Mile Road  
Ferndale, Michigan 48220

JAN 12 2007

Re: K060272

Trade/Device Name: Locobase® Wound and Skin Emulsion  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: October 13, 2006  
Received: October 16, 2006

Dear Mr. Hamer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

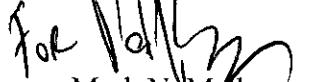
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Richard A. Hamer

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K060272

## INDICATIONS FOR USE

510(k) Number (if known): \_\_\_\_\_

Device Name: Locobase® Wound and Skin Emulsion

### Indications for Use:

Under the supervision of a healthcare professional, for the management and relief of burning, itching and redness associated with atopic dermatitis.

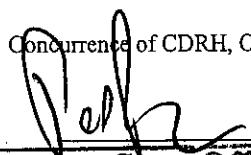
Prescription Use X  
(Per 21 CFR §801.109)

OR

Over-the-Counter Use \_\_\_\_\_

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Devaluation (ODE)

  
(Division Sign-Off)  
**Division of General, Restorative  
and Neurological Devices**

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